DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 28 2004

2341 '04 MAY -7 A9:40

Michael S. Labson
Elizabeth M. Walsh
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004-2401

Re: Docket No. 2003P-0518/CP1

Dear Mr. Labson and Ms. Walsh:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on November 5, 2003, on behalf of Wyeth Pharmaceuticals. Your petition requests that the Agency refrain from approving any generic versions of Rapamune (sirolimus) before April 11, 2006, which is the expiration date of the statutory exclusivity for protected information in the Rapamune labeling.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0518

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